

## 510(k) Summary of Safety and Effectiveness

### 510(k) Summary - PILOT™ Spinal System

**Submitted By:** Life Spine  
2400 Hassell Road, Suite 370  
Hoffman Estates, IL 60195  
Telephone: 847-884-6117  
Fax: 847-884-6118

**510(k) Contact:** Rebecca Brooks  
Life Spine  
2400 Hassell Road, Suite 370  
Hoffman Estates, IL 60195  
Telephone: 847-884-6117  
Fax: 847-884-6118

**Date Prepared:** November 30, 2006

**Trade Name:** PILOT™ Spinal System

**Common Name:** Pedicle screw spinal system

**Classification:** 21 CFR 878.3070  
*Pedicle Screw Spinal System*

**Device Product Code:** *MNI: Orthosis, Spinal, Pedical Fixation*  
*MNH: Orthosis, spondylolisthesis spinal fixation*

**Predicate Device:** DePuy Moss Miami Spinal System K950697  
Stryker Spine TRIO® Spinal Fixation System K052971

**Device Description:**

When implanted in the thoracic, lumbar, and/or sacral spine, the PILOT™ Spinal System provides additional support during spinal fusion. The PILOT™ Spinal System consists of a screws and rods in a variety of shapes and sizes. The PILOT™ Spinal System is manufactured from medical grade titanium and will be sold non-sterile.

**Intended Use of the Device:**

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The PILOT™ Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

When used as a posterior spine thoracic/lumbar system, the PILOT™ Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

**Material:**

The PILOT™ Spinal System is manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6AL-4V-ELI).

**Performance Data:**

Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

**Substantial Equivalence:**

The Life Spine PILOT™ Spinal System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Life Spine  
% Ms. Rebecca Brooks  
Project Coordinator  
2400 Hassell Road, Suite 370  
Hoffman Estates, Illinois 60195

JAN 20 2007

Re: K063601  
Trade/Device Name: Pilot Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: November 30, 2006  
Received: December 4, 2006

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) number (if known): \_\_\_\_\_

### Device Name: PILOT™ Spinal System

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

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Prescription Use   x    
(Part 21 CFR 801 Subpart D)

And/Or

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number   K063661